

Appl. No. : 09/991,721  
Filed : November 13, 2001

### REMARKS

Applicant wishes to thank Examiners Sullivan and Ketter for the courtesy extended to inventors Drs. Bartlett and Moss, attendee Jeffrey Walenta on behalf of National Institutes of Health, and their representative, Nancy Vensko, attorney of record, on July 30, 2003. The Interview Summary Form PTOL-413 summarizes the discussions held at the personal interview. The present response to the outstanding Office Action includes the substance of the Examiner Interview.

#### A. Disposition of Claims

By this amendment, Applicant has canceled Claims 19-24 and 26 without prejudice as being drawn to a nonelected invention, canceled Claim 14 as being superceded by the present embodiment, and canceled Claim 16 as being redundant. Applicant has amended Claims 1-13, 15, 17, 18 and 25, and added Claim 27 as being directed to a tumor cell comprising a new vector for the tumor-directed gene therapy of cancer. Support is found in original Claim 16 (and for new Claim 27 at ¶ 0018, line 3). Thus, Claims 1-13, 15, 17, 18, 25 and 27 are pending. No new matter has been added. Reexamination and reconsideration of the application, as amended, are respectfully requested.

#### B. Free of Informalities

As a preliminary matter, the Patent Office objected to Claim 16 for an informality. The claims must be free of informalities. The verb "is" was found to be missing. Applicant has canceled Claim 16.

#### C. Compliance with Words Alone Requirement

As an additional preliminary matter, the Patent Office rejected Claims 17 and 18 under 35 USC 112, first paragraph, for lack of a deposit. Under MPEP 2402, a deposit is required where words alone cannot sufficiently describe how to make and use the invention in a reproducible manner. The claims have been amended to define the double deletion as being constructed such that the gene for *E. coli lacZ* or enhanced green fluorescent protein (EGFP) is inserted into the thymidine kinase (TK) or virus growth factor (VGF) site. Support is found at ¶ 0086, line 10, and ¶ 0105, line 4. Under this definition, a deposit is unnecessary.

#### D. Compliance with Patentable Subject Matter Requirement

The claims are directed to a tumor cell. Under MPEP 2105, living subject matter is patentable subject matter. See, e.g., USP 5,869,040, attached as Exhibit 1, having our same

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Examiner Ketter as Primary Examiner, claiming a tumor cell. A tumor cell is living subject matter, even if it is going to die. Moreover, by reciting a tumor cell, the claims do not read on a human being. The Patent Office takes the position that a human being is unpatentable subject matter. Thus, by virtue of being drawn to a tumor cell, the claims are directed to patentable subject matter.

**E. Compliance with Utility Requirement**

The Patent Office questioned the utility of a tumor cell that is going to die. Under MPEP 2107, patent applications are to comply with the utility requirement. A tumor cell has utility even if it is going to die. See, e.g., USP 5,869,040, above, claiming a tumor cell that is going to die. A light bulb has utility even if it is going to burn out. See, e.g., Edison Elec. Light Co. v. Novelty Incandescent Lamp Co., 167 F. 977 (3d Cir. 1909) upholding the novelty of Thomas Edison's light bulb patent. A telephone has utility even if it is going to wear out. See, e.g., USP 174,465 and 186,787 to Alexander Graham Bell for the telephone. Alternatively, an invention that is "inoperative" is not a "useful" invention in the meaning of the patent law. Newman v. Quigg, 11 USPQ2d 1340 (Fed. Cir. 1989) (perpetual motion machine). Here, the inventors have created a tumor-selective vaccinia virus by deletion of both its TK and VGF genes. It is capable of selective tumor replication (see Fig. 5) and is significantly less pathogenic than other forms of the virus (see Fig. 4). The utility of this vector is broad in that it may be used as an antitumor agent on its own (see Fig. 6) or by expressing suicide or cytokine genes, tumor-associated antigens, or costimulatory molecules. This is a new vector for the tumor-directed gene therapy of cancer. There is no question of utility.

**F. Compliance with Requirement to Be Free of the Prior Art**

The Patent Office rejected the Claims 1, 2, 5, 6-12, 14, 15 and 25 under 35 USC 102(b) as being anticipated by Bodemer et al. (1991) EP 0 443 335. The Patent Office rejected Claims 1-9, 12, 15 and 25 under 35 USC 102(b) as being anticipated by Paoletti et al. (1992) WO 92/15672. The Patent Office rejected Claims 1, 2, 5, 6-12, 13, 14, 15 and 25 under 35 USC 103(a) as being unpatentable over Bodemer et al. (1991) EP 0 443 335 and further in view of any one of Lee et al. (U.S. Patent No. 5,851,991), Kamb (U.S. Patent No. 5,739,027), Herlyn et al. (U.S. Patent No. 5,622,835), Rotter et al. (WO 94/10575) or Spitsberg et al. (WO 98/08394). The Patent Office rejected Claims 1, 2, 5, 6-12, 14, 15 and 25 under 35 USC 103(a) as being unpatentable over Bodemer et al. (1991) EP 0 443 335 and further in view of any one of JP 55026477, Sawamura et

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al. (U.S. Patent No. 5,962,260), Cheng et al. EP 0 585 960, Boehmert et al. (DE 3411472), Rasmussen et al. (U.S. Patent No. 5,236,838), Kataoka et al. (JP 020655779), or Cheng et al. (U.S. Patent No. 5,981,714). The claims must be free of the prior art. Claim 16 was not rejected. Claim 1 is a duplicate of Claim 16 except that it is directed to the tumor cell itself. All remaining claims, except Claim 25, depend thereon. Claim 25 is a product-by-process claim that is co-extensive with Claim 16. By substituting for Claim 16, the present set of claims is free of the cited art.

### CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

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